



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

August 23, 2001

WARNING LETTER NO. 2001-NOL-50

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Andrew P. Coco, Owner
Coco's Seafood & Fish Company
307 Riverside Drive
Simmesport, Louisiana 71369

Dear Mr. Coco:

We inspected your firm, located at 307 Riverside Drive, Simmesport, Louisiana, on June 12, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and of the Current Good Manufacturing Practice regulations, 21 CFR, Part 110. These deviations, some of which were previously brought to your attention, cause your freshwater fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces with sufficient frequency to ensure control as evidenced by:

- Pitted and nicked cutting board surfaces encrusted with brown and gray foreign material from previous operations;
- Fish weighing scale, along with the chains holding the scale, encrusted with brown residues from previous operations; and,
- Aprons worn by employees encrusted with black residues from previous operations.

During the inspection, our investigator documented numerous insanitary conditions. The inspection found that employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against contamination of those items from microorganisms or foreign substances. For example:

- An employee retrieved processed fish from the dirty floor, rinsed them with water, and returned them to production;
- Employees washed but did not sanitize their hands after handling unsanitized objects and then handled fish; and,
- Employees placed perforated containers, filled with processed fish, directly on the wet floor.

Cleaning and sanitizing utensils and equipment are not conducted in a manner that protects food and food contact surfaces from contamination. For example, your firm does not sanitize processing equipment and utensils after washing.

You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. Failure to exclude fly pests is a potential contributing factor to microbiological contamination in that:

- Numerous flies were observed throughout the processing area landing directly on ceilings, walls, trashcans and other potential sources of contaminants;
- Flies were observed landing on processing equipment and on unprocessed and exposed product; and,
- Flies were observed freely moving into the plant from outdoors and freely moving within the plant between potential sources of pathogens and exposed product.

Dead roaches were observed in the cleaning room and roach excreta pellets were observed on shelves in cabinets above the sink used to clean processing utensils.

In addition, our investigator documented conditions that facilitate unsanitary operations that are associated with the construction and design of your facility. For example:

- Doors leading into the processing facility from the outside do not completely close, resulting in a gap between the doors, and allowing flies to freely enter the plant processing areas from outdoors;
- An open septic pit, located adjacent to the northeast corner of the plant, provides a potential reservoir of pathogens and attracts flies;
- Uncovered floor drains are located in the processing room, ice cooler and store room;
- Water dripped from the ceiling of the ice cooler units directly onto ice that was subsequently placed on processed fish;
- Fish cutting boards, encrusted with brown and gray residues underneath, are nailed to the processing table and cannot be lifted for cleaning;
- Wooden-handled knives are used for processing fish; and,
- A hatchet, with a dirty string wrapped around the handle, was used to process fish.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that at the close of your previous inspection, on November 22, 1999, you made a verbal commitment to correct observed deficiencies, which were virtually the same as those documented on June 12, 2001. Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You may wish to include in your response documentation such as your sanitation records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

A handwritten signature in cursive script, reading "Carl E. Draper".

Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483